

Minutes and Actions for Biologics Subteam Discussion (August 21, 2008)

Attendees:

Lydia Falk, Vada Perkins, Siobhan Stevens Miles, Amy Soslow, Theresa Scotchlas, Erik Marshall, Barbara Kolcz, Mary Beth Wilusz, Melita Glavin, Tom Cantu, Joan Berger, Denise Oliviera, Pearl Rawson, Reina Kalish, Terry Brunone. **Note:** If I've left your name off the attendees' list, please let me know.

WIKI Link: <http://spl-work-group.wikispaces.com/Biologics>

Minutes:

UNII Codes for CBER Active Ingredients

- Sponsor communications containing UNII codes for currently active products have been delayed. CBER is working with ISO to maximize harmonization of substance names and identifying characteristics across the US and Europe (and beyond). As a result, letters were prepared but not yet sent. Alert your regulatory representation to be 'on the lookout' for letters, as they are targeted for mailing in 2008.
- Some names associated with existing UNII codes may change as a result of this harmonization activity, primarily for vaccine active ingredients.
- If you send a note to spl@fda.hhs.gov asking for UNII codes for biologics, you may receive this message:

Unique Ingredient Identifiers (UNII) are a required Drug Listing Data Element (DLDE) necessary to list electronically via the voluntary pilot program as described in the *Guidance for Industry: Providing Regulatory Submissions in Electronic Format-Drug Electronic Drug Establishment and Drug Listing*. The Center for Biologics Evaluation and Research (CBER) is diligently working on developing and assigning UNII codes, as well as other required DLDE codes, for all CBER regulated products captured under 21 CFR 207. The expectation is that all required DLDE codes will be completed prior to the conclusion of the voluntary pilot program on May 31, 2009. Of note: Applicants will be notified through official regulatory correspondence once UNII codes have been assigned to their product.

Hierarchy Worksheets – What's Next

- We've got a Hierarchy Worksheet for the Immune Globulins to review for CBER.

ACTION: If your company has one or more Immune Globulins, look at the worksheet and test out for product. Identify questions that come up that you (or your CMC group) can't answer.

[REPEAT FROM LAST MONTH] Submission of SPL Content of Labeling

- SPL must be submitted with relevant CBER applications (BLA, sBLA, CBE, Annual Report) starting October 15, 2008.
- For the first 12 months of CBER content-of-labeling SPL submission: include SPL with Annual Report – even if there have not been changes. This will result in all relevant products having SPL on file at the FDA within one year after implementation. Consult your Reviewer if there may be a delay in submitting an SPL.
- Draft SPL will be reviewed whether or not it has all UNII codes. If the codes are available, fill them in, as this facilitates the review process.
- Final SPL will not pass validation without UNII codes. It will not be posted on the DailyMed site without them.
- For eCTD submissions, SPL is placed in Module 1, section 14 (Labeling) in Draft Labeling or Final Labeling as appropriate. If review aids such as the Vaccine Hierarchy worksheet or equivalent are included, place them in Module 1 as well.
- For other electronic submissions, make sure that the SPL content of labeling files are in their own \SPL folder. This folder must contain the *.xml file and any accompanying figures.
- Drug Listing and Establishment Registration SPL is required starting June 1, 2009. Prior to that, sponsors are being encouraged to submit these SPL through the Voluntary Pilot Program.

Actions:

All Sponsor Reps:

If you are submitting SPL with upcoming CBER submissions for new, not-yet-approved products, and need UNII codes for your ingredients, alert the Review Division that UNII assignments are needed for one or more active ingredients and moieties.

Sponsor Reps with Immune Globulin products:

Take a look at the worksheet and identify how your product(s) would be characterized.

Next Meeting: October/November 2008 .